UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CONSTRUCTION LABORERS PENSION TRUST OF GREATER ST. LOUIS, ET AL.,

vs.

NEUROCRINE BIOSCIENCES, INC., GARY A. LYONS, PAUL H. HAWRAN, WENDELL D. WIERENGA, HENRY Y. PAN, RICHARD F. POPS, and WYLIE W. VALE,

Defendants.

CASE NO. 07CV1111-IEG-RBB

ORDER:

(1) GRANTING DEFENDANTS' MOTION TO DISMISS CONSOLIDATED AMENDED COMPLAINT; (Doc. No. 36)

(2) GRANTING PLAINTIFFS LEAVE TO AMEND;

(3) GRANTING IN PART AND DENYING IN PART DEFENDANTS' REQUESTS FOR JUDICIAL NOTICE; (Doc. Nos. 37 & 48)

(3) GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTIONS TO STRIKE (Doc Nos. 41 & 52).

Presently before the Court are: (1) a motion to dismiss the consolidated amended complaint in its entirety, filed by defendants; (2) a motion to strike defendants' request for judicial notice, filed by plaintiffs; and (3) a motion to strike defendants' supplemental request for judicial notice, filed by plaintiffs. The lead plaintiffs are Charles N. Seiji and Raymond J. Mertz. Defendants are Neurocrine Biosciences, Inc., Gary A. Lyons, Paul H. Hawran, Wendell D. Wierenga, Henry Y. Pan, Richard F. Pops, and Wylie W. Vale. For the following reasons, the Court: (1) grants defendants' motion to

dismiss the consolidated amended complaint; (2) grants plaintiffs leave to amend; (3) grants in part and denies in part defendants' requests for judicial notice; and (4) grants in part and denies in part plaintiffs' motions to strike.

BACKGROUND

A. Factual Background

This action alleges a common scheme and course of conduct by Neurocrine Biosciences, Inc. ("Neurocrine"), its officers, and its directors to defraud investors in violation of Section 10(b) and Section 20(b) of the Securities Exchange Act of 1934. Plaintiffs represent a purported class of investors who purchased Neurocrine stock between February 10, 2005 and June 23, 2006 ("the class period").

Neurocrine engages in the development and discovery of drugs for the treatment of neurological and endocrine-related diseases and disorders in the United States. (Consolidated Amended Complaint ("Complaint") ¶ 32.) In 1998, Neurocrine acquired the rights to a drug called "indiplon" which the company claimed could be used for the treatment of insomnia. (Id. ¶¶ 33-34.) A modified-release ("MR") formula of the drug could potentially maintain a patient's sleep, differentiating indiplon from the other available insomnia medications only approved to induce sleep. (Id. ¶¶ 35, 55 & 59.)[1] Neurocrine also indicated indiplon could be approved without the "short-term" label which restricts use of other insomnia medications to only seven to ten days. (Id. ¶ 36.)

Pharmaceutical companies seeking Food and Drug Administration ("FDA") approval of a new drug must establish the drug is safe and effective. (Id. ¶ 28.) After completing three phases of human clinical trials, the company submits a New Drug Application ("Application") to the FDA. The agency then determines "if clinical trials and other data demonstrate that the drug is effective for its intended use and that the established benefits of the drug outweigh its known risks." (Id. ¶ 29.) If the data is incomplete, inaccurate, biased, or if it suggests the product is unsafe or ineffective, the FDA will not approve the Application. (Id. ¶ 30 (citing 21 C.F.R. §

[1]The company also developed an immediate-release ("IR") formulation, which the FDA approved in 5 and 10 mg doses. Neurocrine focused primarily on MR indiplon during the class period, and references to "indiplon" are to MR indiplon unless otherwise noted.

314.125(b)(3), (4) & (5)).)

In December of 2002, Neurocrine entered into a collaboration agreement with "pharmaceutical giant" Pfizer, Inc. to pursue FDA approval of indiplon. (Complaint ¶¶ 41-42.) During the class period, Neurocrine focused primarily on the development and commercialization of indiplon, and had no other major products or sources of funding. Plaintiffs allege the company encountered problems with MR indiplon in the clinical testing of 20 and 30 milligram doses, specifically "tolerance" (decreasing efficacy of the drug over time) and "next-day drowsiness." (E.g., id. ¶¶ 53-54.) Because of these problems, defendants decided not to file an Application for the 20 and 30 mg doses. (Id. ¶ 66.) Plaintiffs support these allegations with details provided by anonymous witnesses. (Id. ¶¶ 75-78.)

Defendants then performed two studies of a 15 mg dose, in what plaintiffs allege was a futile attempt to muster any support for the new dose. (Id. ¶¶ 66 & 77.) Publically, Neurocrine reported it completed 70 trials with over 7000 subjects, and repeatedly emphasized the quantity of data supporting the Application. (E.g., id. ¶¶ 62-63.) On November 22, 2004, Neurocrine announced the submission of the Application for MR indiplon. (Id. ¶ 72.) On December 21, 2004, the company announced the FDA was having technological problems accessing the Application, but Neurocrine re-filed in a better format in May of 2005. (Id. ¶ 73.) Plaintiffs allege defendants took advantage of the opportunity to re-file by adding additional data to the Application from a second study of the 15 mg dose,[2] despite reassuring the public the Application was complete and still "on track" for FDA approval. (Id. ¶ 80.)

The complaint includes an anonymous technical writer's report that Neurocrine's "VP of Regulatory Affairs and VP of Clinical Development for MR indiplon told the executive team that there was insufficient data at the 15 mg dose, but defendants ignored the warning and submitted the MR Application knowing it contained insufficient data." (Id. ¶ 81(a).) Plaintiffs claim defendants made false statements when they spoke optimistically about the chance of success of the Application and claimed it was complete and well-supported. (Id. ¶ 81(a)-(b).) Plaintiffs also

[2] At oral argument, the parties disagreed as to whether the amended Application contained a second or a third study of 15 mg indiplon. Plaintiffs argued the submission of a third study at this stage could imply communications from the FDA requesting additional data. The complaint is unclear as to whether this was a second or third 15 mg study.

allege defendants made material misrepresentations by stating MR indiplon was safe and efficacious, in light of the tolerance and next-day drowsiness problems alleged above. (Id. ¶¶ 81(c)-83.)

While the FDA considered the indiplon Application, defendants continued to make optimistic statements regarding FDA approval. Plaintiffs identify and quote many such statements in the complaint. Representative examples include the statements by defendants Lyons and Wierenga in an October 24, 2005 conference call. Lyons stated "indiplon regulatory is moving according to schedule. We remain optimistic in receiving a first cycle approval on our PDUFA [Prescription Drug User Fee Act] dates . . . so everything is tracking according to plan in that respect." (Id. ¶ 87.) Wierenga added "the program, as Gary noted, is proceeding on track with the agency. And we are looking forward to an expansion of opportunities for indiplon post approval as we expand the Phase 4 opportunities for the drug." (Id.) When asked about his confidence regarding the PDUFA dates, Lyons explained:

> The confidence is simply I think we have done the most comprehensive registration trial and program, have submitted a complete package, have obviously tracked other submissions that have gone to the neuropharm agencies that we don't think are as robust as the indiplon data package, so we remain optimistic that we have identified and done the necessary trials to over come any obstacles.

(Id.)

Before the market opened on May 16, 2006, Neurocrine publically announced the FDA had issued a "non-approvable" letter regarding 15 mg indiplon.[3] (Id. ¶ 96.) A non-approvable letter signifies deficiencies in the Application such that approval in the future may require additional data or additional clinical trials. (Id. ¶ 31.) During a conference call on May 16, 2006, defendant Lyons explained "the FDA response was a surprise to us" but characterized it as a "short-term setback." (Id. ¶ 97.) According to a later press release by the company, the FDA's "non-approvable" letter regarding 15 mg indiplon requested the company "reanalyze certain safety and efficacy data." Plaintiffs also allege the letter "questioned the sufficiency of the Company's objective sleep maintenance clinical data for the 15 mg tablet in view of the fact that the majority of the Company's indiplon tablet studies were conducted with doses higher than 15 mg." (Id. ¶¶

[3]In the same press release, Neurocrine reported FDA approval of the 5 and 10 mg doses. (Complaint ¶ 96.)

99 & 101.)

This announcement caused a 62% drop in the stock price, which sank from $54.54 to $20.76 per share. On June 22, 2006, Neurocrine announced Pfizer terminated its collaboration agreement with Neurocrine. As a result of this news, Neurocrine's stock fell to $9.85 per share.

During the class period, Gary A. Lyons was Neurocrine's Chief Executive Officer and President; Paul H. Hawran was the Executive Vice President and Chief Financial Officer; Wendell D. Wierenga was the Vice President of Research and Development; Henry Y. Pan was the Executive Vice President and Chief Medical Officer; Richard F. Pops was a director, and Wylie W. Vale was a director and Chief Scientific Advisor. (Id. ¶¶ 19-24.) Plaintiffs allege defendants Lyons, Hawran, Pops and Vale sold shares of Neurocrine's stock during the class period. (Id. ¶¶ 111-12.) Plaintiffs also allege defendants Lyons, Hawran and Wierenga received performance-based bonus payments linked to achieving goals for indiplon and other drugs in 2005.

B. Procedural Background

Plaintiffs initially filed this action on June 19, 2007, and filed the operative complaint on November 30, 2007. (Doc. No. 33.) On January 11, 2008, defendants filed a motion to dismiss the complaint (Doc. No. 36), and an accompanying request for judicial notice (Doc. No. 37). On February 28, 2008, plaintiffs filed an opposition to the motion. (Doc. No. 40.) On March 10, 2008, plaintiffs filed a motion to strike defendants' request for judicial notice. (Doc. No. 41.) On March 24, 2008, defendants filed an opposition to the motion to strike (Doc. No. 46), and a reply in support of their motion to dismiss (Doc. No. 47), along with a supplemental request for judicial notice. (Doc. No. 48.) On March 25, 2008, plaintiffs filed a motion to strike defendants' supplemental request for judicial notice (Doc. No. 52), and on March 26, 2008, defendants opposed that motion (Doc. No. 53). On March 28, 2008, plaintiffs filed a reply in support of their first motion to strike. (Doc. No. 54.) On April 15, 2008, plaintiffs filed a reply in support of their second motion to strike. (Doc. No. 56.)

The Court heard oral argument at 9:30 a.m. on April 22, 2008. Michael Dowd, Daniel Drosman, Jennifer Keeney and Karen Reilly appeared on behalf of plainitffs. William Grauer, Mary Kathryn Kelley, and Ryan Blair appeared on behalf of defendants.

DISCUSSION

Legal Standards

1. Rule 12(b)(6) Motion to Dismiss

A motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the claims asserted in the complaint. Fed. R. Civ. Proc. 12(b)(6); Navarro v. Block, 250 F.3d 729, 731 (9th Cir. 2001). The court must accept all factual allegations pleaded in the complaint as true, and must construe them and draw all reasonable inferences from them in favor of the nonmoving party. Cahill v. Liberty Mutual Ins. Co., 80 F.3d 336, 337-38 (9th Cir. 1996); Mier v. Owens, 57 F.3d 747, 750 (9th Cir. 1995) (citing Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987).

2. Pleading Requirements for Private Securities Actions

A claim under Section 10(b) of the Securities and Exchange Act of 1934 or Rule 10b-5 promulgated thereunder has five elements: (1) a misrepresentation or material omission; (2) materiality; (3) scienter; (4) reliance; and (5) causation. McCormick v. Fund Am. Cos., 26 F.3d 869, 875 (9th Cir. 1994).

Pursuant to the Private Securities Litigation Reform Act (hereinafter "PSLRA"), plaintiffs in securities actions must plead fraud with particularity and:

> specify each statement alleged to have been misleading, the reason or reasons why the statement or omission is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1).

Plaintiffs must also plead scienter under the PSLRA's standard: "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. § 78u-4(b)(2). The required state of mind is one of "deliberate recklessness." In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 975 (9th Cir. 1999). "[R]ecklessness only satisfies scienter under § 10(b) to the extent that it reflects some degree of intentional or conscious misconduct." Id. at 977; see also Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1230 (9th Cir. 2004).

The Ninth Circuit "incorporate[s] the dual pleading requirements of §§ 78u-4(b)(1) and (b)(2) into a single inquiry, because falsity and scienter are generally inferred from the same set of facts." In re Read-Rite Corp. Sec. Litig., 335 F.3d 843, 846 (9th Cir. 2003); Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001). In assessing whether a plaintiff has sufficiently pleaded scienter, the court must consider "whether the total of plaintiffs' allegations, even though individually lacking, are sufficient to create a strong inference" of scienter. No. 84 Employee-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 938 (9th Cir. 2003). "The requirement to plead all the facts with particularity means that a plaintiff must provide a list of all relevant circumstances in great detail." Read-Rite, 335 F.3d at 846 (internal quotations omitted); Silicon Graphics, 183 F.3d at 984. The complaint is sufficient "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs v. Makor Issues & Rights, Ltd., ___ U.S. ___, 127 S. Ct. 2499, 2510 (2007).

3. Judicial Notice

Rule 201 of the Federal Rules of Evidence allows courts to take judicial notice of matters that are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The Court may take judicial notice on a motion to dismiss under Rule 12(b)(6). Lee v. City of Los Angeles, 250 F.3d 668, 688-89 (9th Cir. 2001); Silicon Graphics, 183 F.3d at 986.

Analysis

Defendants' motion to dismiss challenges the sufficiency of plaintiffs' allegations of scienter, falsity, and loss causation. Defendants also argue their allegedly false statements are protected by the safe harbor provisions of the PSLRA.

I. Falsity & Scienter

Plaintiffs allege defendants knew the FDA would not approve 15 mg indiplon because there was insufficient data. Most of the clinical data supporting the Application involved the 5, 10, 20, and 30 mg doses of indiplon, but Neurocrine included at least two 15 mg studies. Plaintiffs argue defendants fraudulently stated the data was comprehensive and provided ample support for

an Application they expected to succeed. Defendants argue the more compelling inferences are that defendants were honestly optimistic about the success of indiplon, defendants believed the data adequately supported the 15 mg Application, and the FDA did not approve the Application because of the independent judgment of its scientists as to the sufficiency of the data. Considering plaintiffs' allegations individually and in their entirety, the Court concludes the complaint fails to raise a compelling inference of scienter.

a. The "Switch" to 15 mg indiplon

Plaintiffs rely on several decisions of other courts upholding complaints alleging a pharmaceutical company made false representations regarding FDA approval of a drug. In those cases, the pharmaceutical company communicated with the FDA about the same problems which ultimately caused the FDA not to approve the drug. The FDA's communications supported the compelling inference defendants knew approval was unlikely. Warshaw v. Xoma Corp., 74 F.3d 955 (9th Cir. 1996) (finding compelling inference of scienter based on allegations defendants received negative communications from the FDA while continuing to assure the public the FDA would approve the drug); Yanek v. Staar Surgical Co., 288 F. Supp. 2d 1110, 1124-25 (C.D. Cal. 2005) (same); In re Amylin Pharms., Inc., Sec. Litig., No. 01cv1455 BTM, 2002 WL 31520051 at *3 (S.D. Cal. Oct. 10, 2002) (amended other grounds on denial of rehearing by 2003 WL 21500525 (S.D. Cal. May 1, 2003)) (same).

At oral argument, plaintiffs conceded their complaint contains no allegations of FDA communications. Instead, plaintiffs argued the Court should infer scienter because Neurocrine's decision to pursue FDA approval of the 15 mg dose was a new plan, adopted after problems appeared at higher doses. These allegations of a "switch" are not comparable to a communication from the FDA expressing serious concerns about the sufficiency of the data. A change in approach does not indicate the new approach is likely to fail. The Ninth Circuit Court of Appeals has rejected an inference of scienter based on the allegation defendants secretly changed an accounting practice. In re Vantive Corp. Sec. Litig., 283 F.3d 1079 (9th Cir. 2002). While it was unclear whether the accounting practice had changed, the court emphasized the change itself was not a "fact[] making the [new] practice fraudulent or misleading." Id. at 1090. Without "specific

contemporaneous conditions known to the defendants that would strongly suggest that the defendants understood" the new accounting method was misleading, the court found no inference of scienter. Id. at 1091; see also In re Lantronix, Inc., No. 02cv3899 PA, 2003 WL 23198818 at *6 (C.D. Cal. Dec. 31, 2003) (concluding no inference of scienter arose from change in accounting practices, despite allegations the change was made in order to conceal earlier improper accounting decisions).

Similarly, in this case, the complaint must allege facts regarding defendants' knowledge during the class period. Rather than simply alleging the 15 mg dose reflected a change in the company's approach, plaintiffs must plead "specific contemporaneous conditions" which "strongly suggest" defendants knew the 15 mg dose would not be approved.

b. Warning on the Sufficiency of the Data

The strongest allegation supporting scienter comes from an anonymous witness, a "technical writer," who claims the Vice President of Regulatory Affairs and Vice President of Clinical Development warned "the executive team" the 15 mg dose was not supported by sufficient data. (Complaint ¶ 81(a).) This allegation does not contain necessary corroborating detail. Without specifics such as the time and place, and the anonymous witness's basis for knowledge and involvement in the conversation, the Court cannot infer defendants secretly credited this warning despite their public expressions of confidence in the Application. In re Daou Sys., Inc., 411 F.3d 1006, 1015 (9th Cir. 2005); see also In re InfoSonics Corp. Sec. Litig., No. 06cv1231 BTM, 2007 WL 2301757 at *4 (S.D. Cal. Aug. 7, 2007). The Court finds this allegation supports scienter, but is lacking in particularity.

c. The FDA's Guidelines

Defendants argue the more compelling inference arising from the complaint is that they reasonably believed the studies completed on other indiplon doses, combined with the two 15 mg studies, provided ample support for the Application. In support of this argument, defendants

request judicial notice of several FDA documents.[4] The FDA's guidelines indicate a drug can be approved based on studies of other doses or formulations of the drug. (Defendants' Supplemental Request for Judicial Notice ("RJN"), Ex. AP.)

Plaintiffs argue the Court may not consider any documents not referenced in the complaint in deciding a motion to dismiss. Documents publically available to a reasonable investor during the class period, however, are an appropriate subject of judicial notice. In re Copper Mountain Sec. Litig., 311 F. Supp. 2d 857, 864 (N.D. Cal. 2004).

Defendants' position is strongly supported by the decision in Noble Asset Management v. Allos Therapeutics, Inc., No. 04cv1030 RPM, 2005 WL 4161977 (D. Colo. 2005). In that case, the court granted defendants' request for judicial notice of FDA documents explaining the agency's policies and procedures because:

> plaintiff's fraud claim is premised on the theory that the defendants misrepresented the strength of the Allos [application] by failing to disclose factors that might lead the FDA to reject the application. [The documents] are public documents by the FDA related to its process for reviewing new drug applications and that process is central to an evaluation of the claims made in this case.

Id. at *2; see also In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953 (D. Md. 1995).[5]

In this case, an understanding of the basis for FDA decisions is also critical, as illustrated

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[4]The Court will consider defendants' requests for judicial notice in conjunction with each argument the exhibits are intended to support. Plaintiffs have moved to strike many of the exhibits in defendants' requests for judicial notice. While plaintiffs' first motion to strike was not filed in a timely manner, the Court must still sua sponte consider the appropriateness of judicial notice. The Court reminds plaintiffs future untimely filings may be disregarded.

[5]In Medimmune, the court explained:

> Medical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results. Although the [FDA] Advisory Committee may have disagreed, there is nothing to suggest that Defendants could not reasonably have entertained the opinion, for example that the concentration of test results at the Denver site was a function of either or both the altitude or the higher proportion of bronchopulmonary dysplasia patients at that site. Simply to aver that the Advisory Committee, based on theoretical (not to say inappropriate) concerns, eventually challenged the company's opinion, is not to say that Defendants should have had knowledge of the theoretical statistical limitations on their assumptions.

873 F. Supp. at 966-67.

Although the Court in In re Amylin Pharms., Inc., Sec. Litig., No. 01cv1455 BTM, 2003 WL 21500525 (S.D. Cal. May 1, 2003) (hereinafter Amylin II), disagreed with Medimmune's holding on another basis, id. at * 8, the decision has been cited approvingly by other courts in this district discussing inferences of scienter based on the likelihood of FDA approval. See DeMarco v. Depotech Corp., 149 F. Supp. 2d 1212, 1225 (S. D. Cal. 2001) (citing Medimmune to support the conclusion a securities fraud claim may not be based on "a legitimate difference in opinion as to the proper statistical analysis"); Martin v. Maxim Pharms., Inc., No. 00cv2507 JM, Order Granting Motion to Dismiss, slip op. at 10 (S.D. Cal. Dec. 2, 2003) (attached as Ex. C to Defendants' RJN) (citing Medimmune and concluding "the FDA's concerns, criticisms, and recommendations regarding the study design do not satisfy the scienter requirement").

by the complaint's detailed discussion of the FDA approval process.[6] Acccordingly, the Court considers the guidelines insofar as they explain public understanding of the FDA approval process.[7] Specifically, "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products" explains the FDA considers studies of other doses when evaluating a proposed dose.[8] The indiplon Application contained two studies of the 15 mg dose and additional studies of other doses, and the guidelines suggest this amount of data could be more than adequate. This understanding of the FDA approval process tends to negate the inference defendants knew the FDA would not approve the Application because most of the data was from studies of doses other than 15 mg.

d. Insider Trading

Insider trading is suspicious when it is "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." Vantive Corp., 283 F.3d at 1080 (internal citations omitted). The Court takes judicial notice of defendants' Forms 3, 4, and 5 filed with the Securities and Exchange Commission ("SEC") before and during the class period.[9] These filings show defendants' stock sales during the class period are not suspicious based on the timing, the amount and percentage of shares sold, and the context of

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[6] E.g. Complaint ¶¶ 28-29, 30 (citing 21 C.F.R. § 314.125(b)(3), (4) & (5)), 31, 81, & 92. As defendants noted at oral argument, the complaint omitted portions of defendants' statements which explained data from one dose would cross over to other doses. Thus the complaint omits statements made by defendants which negate scienter, and the full content of those documents may be considered under the incorporation by reference doctrine.

[7] The Court declines to judicially notice Exhibits B and I because defendants do not establish their content before or during the class period. (Defendants' RJN Exs. B & I (providing screenshots of websites dated after class period)).

[8] The document, dated May 1998 and available on the FDA's website through the class period, states it "represents the agency's current thinking" on new drug applications but is not binding. (Defendants' RJN, Ex. AP at 1, n.1.) The guidelines explain the FDA generally requires "at least two adequate and well-controlled studies." (Id. at 3.) The FDA explains a dose may be supported by clinical tests entirely or mostly on other doses of the drug:

> Dose-response relationships are generally continuous such that information about the effectiveness of one dose, dosage regimen, or dosage form is relevant to the effectiveness of other doses, regimens, or dosage forms. . . . Even if blood levels are quite different, if there is a well-understood relationship between blood concentration and response, including an understanding of the time course of that relationship, it may be possible to conclude that a new dose, regimen, or dosage form is effective on the basis of pharmacokinetic data without an additional clinical efficacy trial.

(Id. at 8.)

[9] Defendants' RJN Exs. O-S. Judicial notice of these filings is appropriate under the "incorporate by reference" doctrine, even if the complaint does not actually mention the filings as the source of plaintiffs' information regarding defendants' stock trades. See InfoSonics Corp., 2007 WL 2301757 at *5, n 2.

the sales. Lyons sold 6.2% of his total holdings during the class period, less than he sold in 2004 or 2003. A margin call after Neurocrine publically disclosed the FDA's non-approvable letter caused 90% of Hawran's sales. Finally, Pops and Vale's sales were not suspicious because no allegations connect Pops and Vale to any of the information about indiplon or any misstatements. Moreover, Pops sold only 23.4% of his holdings, six months before FDA rejection of indiplon. Vale sold less Neurocrine stock during the class period than in 2003 or 2004. His class period sales represented 14% of his holdings and were made pursuant to a 10-b5-1 trading plan he entered into ten months before the FDA's non-approvable letter.[10] Accordingly, the Court finds the insiders' stock sales were not suspicious and do not support an inference of scienter.[11]

e. Miscellanous Facts

Plaintiffs argue several other facts support an inference of scienter: defendants' incentives to receive bonus compensation from Neurocrine, the company's incentive to obtain milestone payments from Pfizer, the small size of the company, and the importance of indiplon to the company. None of these facts strongly supports scienter.[12]

The receipt of bonus compensation by defendants Lyons, Harwan, and Wierenga during the class period does not bolster plaintiffs' allegations. As the Ninth Circuit has explained, "routine business objectives, without more, cannot normally be alleged to be motivations for

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[10]Where an insider's trading is scheduled under a Rule 10b-5 trading plan in place before the alleged inside information is received, no inference of scienter arises. See InfoSonics Corp., 2007 WL 2301757 at *5; see also Howard v. Everex Sys., Inc., 228 F.3d 1057, 1066 (9th Cir. 2000) (finding insider's sales not suspicious because made pursuant to a divestiture program entered into before class period).

[11]Although the complaint contained detailed allegations which inflated the significance of defendants' stock sales, plaintiffs' opposition to the motion to dismiss did not respond to defendants' lengthy explanation of the lack of the suspiciousness in the stock sales.

[12]The Court also rejects one of defendants' proffered arguments against scienter. Defendants request judicial notice of Neurocrine's post-class period SEC filings to prove defendants' actions during the class period. Specifically, defendants argue the infusion of substantial sums of money into the clinical trials and the Application during the class period negates the inference defendants knew the Application would fail. (Defendants' RJN Exs. A & F.) Judicial notice of facts "subject to reasonable dispute" is improper. Defendants' report of significant investment in indiplon during the class period does not place this fact out of the realm of reasonable dispute. Accordingly, the Court grants plaintiffs' motion to strike the exhibits offered for this purpose. Additionally, the Court finds Neurocrine's financial commitment to the Application filing would only provide a weak argument against scienter. See Amylin II, 2003 WL 21500525 (finding compelling inference that defendants misrepresented the riskiness of the product's approval while the company invested large sums in the hope the product would be approved); but see Martin, Defendants' RJN, Ex. C at 14 (finding it "illogical to infer that Defendants needed money to complete the Phase III trials while, at the same time, knowing that [the product] was ineffective and unsafe and that it would spend funds on pursing a futile clinical trial.").

fraud." Lipton v. Pathogenesis, 284 F.3d 1027, 1038 (9th Cir. 2002).

The Court also rejects plaintiffs' argument defendants' incentives to obtain "milestone" payments from Pfizer support scienter. Misleading the market could not have benefitted Neurocrine's relationship with Pfizer, because Pfizer had access to the same inside information as defendants. (Complaint ¶ 12.)

Finally, the Court considers plaintiffs' claims the small size of Neurocrine and the importance of indiplon, its primary product during the class period, substantiate their allegations defendants knew of the problems with indiplon and the inadequacy of the 15 mg data. The only particularized allegation that any individual at the company believed the Application was not supported by sufficient data is the claim of the anonymous witness regarding a warning to the executive team. The importance of indiplon to the company may make it more likely defendants knew about and considered this warning. Other considerations, such as the timing of the warning, to whom it was made, and other details discussed previously are much more important in evaluating the warning, and are missing from the complaint. These allegations provide only weak support for the scienter inference. Cf. In re Ligand Pharms., Inc. Sec. Litig., No. 04-1620 DMS, 2005 WL 2461151 at *15 (S.D. Cal. Sept. 27, 2005) (noting the importance of a product does not impute awareness of all possible problems and their significance to all defendants); Read-Rite, 335 F.3d at 848-49 (finding the importance of the product to the company raises a "reasonable" but not a "strong" inference that officers responsible for that product would have known about problems at the time of false statements).

f. The Totality of the Allegations

As noted above, most of plaintiffs' allegations do not support the inference defendants knew the FDA would find the data regarding the 15 mg dose insufficient. The allegation the 15 mg dose was a "new" dose does not support the inference of scienter. The most particularized allegation is that a warning was made to "the executive team." As described above, this does not create an inference of scienter nearly as strong as the inference defendants "had a reasonable basis for their optimistic statements concerning the drug's efficacy, quality of life and economic benefits." DeMarco, 149 F. Supp. 2d at 1224-25. In DeMarco, the court dismissed the complaint

because it did not include "facts explaining why the difference between the earlier and later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." Id. at 1232 (quoting Padnes v. Scios Nova, Inc., No. 95-1693, 1996 WL 539711 at *5 (N.D. Cal. Sept. 18, 1996)) (additional citations omitted).[13] In this case, the only such fact is, again, the anonymous witness's report regarding one warning as to the sufficiency of the data. Cf. Martin, Defendants' RJN, Ex. C at 13 n.1 (finding insufficient the allegation defendants received progress reports on clinical trials because "this allegation fails to allege that the [reports] provided sufficiently detailed information to meaningfully analyze and forecast the end results of the study.").[14]

The allegations in In re Dura Pharmaceuticals, Inc. Securities Litigation, 452 F. Supp. 2d 1005 (S.D. Cal. 2006) (hereinafter Dura II), which the court found insufficient to support a compelling inference of scienter, contain more detail than plaintiffs supply in the complaint. In Dura II, plaintiffs alleged defendants received internal reports informing them of problems with the products and highlighting the objections by the company's engineers to continuing clinical trials. Plaintiffs also alleged defendants held weekly meetings at which they learned about the product's problems. Plaintiffs claimed minutes of those meetings were kept and reflect defendants posed specific inquiries regarding the problems. One of the defendants allegedly did not want to file the Application because he believed it would not be approved, but other defendants "overruled" him. Moreover, the Dura II defendants also allegedly ignored the FDA's warnings regarding the product's problems. Id. at 1025. Despite the particularity of these allegations, the

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[13]Plaintiffs attempt to distinguish DeMarco because defendants in that case did not learn of the falsity of their representations until after the end of the class period. 149 F. Supp. 2d at 1212. Plaintiffs' complaint does not allege the timing of the warning to the executive team, and no other allegations raise the inference defendants knew the FDA would not approve indiplon prior to receiving the non-approvable letter.

[14]Plaintiffs rely heavily on a brief, unpublished decision from the District of Utah, In re NPS Pharmaceuticals, Inc. Securities Litigation, No.06cv570, 2007 WL 1976589 (D. Utah July 3, 2007). That decision did not specifically detail the facts which supported the inference of scienter, but found adequate support based on statements by six anonymous witnesses "confirming the defendants' knowing concealment of certain information and false dissemination of other information." Id. at *6. No such support is present in this case. To the extent plaintiffs argue under NPS Pharmaceuticals the Court should not scrutinize plaintiffs' factual allegations, the Court disagrees and evaluates whether the inference stemming from these allegations is "compelling" and "cogent." See, e.g., DeMarco, 149 F. Supp. 2d at 1225; Dura II, 452 F. Supp. 2d at 1025.

Court required additional corroborating detail regarding the source of plaintiffs' information. In this case, plaintiffs' only specific contemporaneous allegation is that a Vice President warned the "executive team" the data did not support the 15 mg dose. This is significantly less compelling than the Dura II allegations, which were also inadequate under the PSLRA.

Accordingly, the Court finds plaintiffs' allegations of scienter and falsity do not meet the pleading requirements of the PSLRA. Because the complaint, evaluated in its entirety, lacks particularized facts supporting a strong inference defendants knew the 15 mg data was insufficient and would not be approved by the FDA, plaintiffs' claims under Section 10(b) of the Securities and Exchange Act must be dismissed. Additionally, plaintiffs' claims under Sections 20(b) fail without an underlying violation of Section 10(b). Paracor Fin., Inc. v. Gen. Elec. Capital Corp., 96 F.3d 1151, 1161 (9th Cir. 1996).

II. The PSLRA Safe Harbor for Forward-Looking Statements

Defendants also argue the statements in the complaint are protected by the safe harbor provisions of the PSLRA. See 15 U.S.C. § 78u-5(c)(1). Under the PSLRA safe harbor, plaintiffs may not base a securities claim on a forward-looking statement "if and to the extent that the forward-looking statement is identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." Id.

While plaintiffs allege defendants made many false statements, the Court focuses on the statements made regarding the completeness of the indiplon Application and the support for the Application in the clinical data.[15] In most of the statements, defendants expressed confidence the FDA would approve the application due to the large number of clinical trials. The statements which simply anticipate success for the Application are clearly forward-looking statements. (Complaint ¶ 91 ("we had been anticipating a full commercialization later this year, and we are not changing that forecast") & ¶ 94 (expressing the belief the Application was on track for approval).)

[15]The Court will not discuss the other allegedly false statements regarding tolerance and next-day drowsiness at length because plaintiffs do not allege the FDA's non-approvable letter was based on those concerns. Insofar as plaintiffs allege defendants misrepresented then-existing safety concerns, these statements are not covered by the PSLRA safe harbor.

Defendants made both of these statements during conference calls in which they referred listeners to the risk factors contained in Neurocrine's SEC filings.[16] The safe harbor allows oral statements to incorporate risk factors by reference. 15 U.S.C. § 78u-5(c)(2)(B). Accordingly, the Court considers whether the risk factor warnings in Neurocrine's SEC filings contained "meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1).

Neurocrine repeatedly warned investors about the risk the FDA would not approve indiplon.[17] Neurocrine's 10-Q for the third quarter of 2005 referenced the risk "that the product will be ineffective or unsafe during clinical trials, [or] will fail to receive necessary regulatory approvals." (Defendants' RJN, Exhibit AL at 14.)[18] Neurocrine further explained the FDA could find the Application "incomplete or insufficient." (Id. at 15.) Neurocrine also noted the company has "limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals." (Id.) These warnings explained the precise risk which materialized when the FDA found the Application insufficient. Accordingly, the Court finds the purely forward-looking statements contained in the complaint are within the PSLRA's safe harbor and are not actionable.

In more complex statements, however, defendants explained they believed the FDA would approve the Application because of the comprehensiveness of the data. (Complaint ¶ 80 ("we feel very comfortable this is a very complete application and one that is able to be navigated with ease by the agency" and explaining the strength of the data); ¶ 84 (calling the submission an "exciting milestone" and explaining the Application "is supported by one of the most comprehensive

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[16] See Defendants' RJN, Ex. AC at 2 (reminding listeners of safe harbor cautions "contained in the company's SEC filings, including but not limited to the Company's Annual Report on Form 10-K and quarterly reports on Form 10-Q") and Ex. AD at 1 (same).

[17] See Defendants' RJN, Exs. G, J-M, T, U, W-Z, & AA-AO. Plaintiffs oppose judicial notice of the risk warnings which were given in connection with the allegedly misleading statements in press releases and conference calls cited in the complaint. The PSLRA requires the Court to consider these statements. 15 U.S.C. § 78u-5(e) ("On a motion to dismiss . . . the court shall consider . . . any cautionary statement accompanying [a] forward-looking statement, which [is] not subject to material dispute, cited by the defendant."). Plaintiffs essentially argue the merits of the safe harbor's application, not the propriety of judicial notice. Accordingly, plaintiffs' motions on this basis are denied, and the Court takes judicial notice of the risk warnings contained in plaintiffs' SEC filings, press releases, and conference calls.

[18] Neurocrine filed this 10-Q on November 9, 2005, so it was available at the time of the January 23, 2006 and February 24, 2006 conference calls referenced in paragraphs 91 and 94 of the complaint.

clinical trial programs in insomnia and demonstrates the long-term safety and efficacy profile of indiplon in helping patients with sleep onset and sleep maintenance problems"); ¶ 87 (claiming that "indiplon regulatory is moving according to schedule," that the company continues to expect approval by the FDA, and that the company is confident the data is comprehensive).) If these statements were "assumptions" underlying forward-looking statements, then they are within the safe harbor provision. 15 U.S.C. § 78u-5(i)(1) (defining "forward-looking statement" to include "any statement of the assumptions underlying or relating to any" forward-looking statement). If the defendants stated "presently-existing facts," the statements are not covered by the safe harbor. In re Leapfrog Enters., Inc. Sec. Litig., 527 F. Supp. 2d 1033, 1046 (N.D. Cal. 2007) ("Statements of present or historical facts are generally not considered forward-looking.").

Other courts have struggled with this distinction. For example, in Amylin Pharmaceuticals, Judge Moskowitz found the company's statements regarding sufficiency of the data supporting the Application and the results of the clinical trials were "underlying" assumptions and thus protected by the safe harbor. 2002 WL 31520051 at *9. But Judge Moskowitz later reversed his prior decision on that point, finding the statements were not forward-looking. Amylin II, 2003 WL 21500525 at *5. In South Ferry LP No. 2 v. Killinger, 399 F. Supp. 2d 1121 (W.D. Wash. 2005), the court adopted a similar approach, finding statements were not protected by the safe harbor because they "also function[ed] as communications of current expectations and are actionable as such." Id. at 1133.[19] Another court explained "[a] present tense statement can be considered forward-looking 'as long as the truth or falsity of the statement cannot be discerned until some point in time after the statement is made.'" LeapFrog Enters., 527 F. Supp. 2d at 1046 (internal citation omitted).

Defendants' statements in this case relating to the comprehensiveness of the data could have been false when made. If defendants knew the Application was inadequate, these statements misrepresented their "current expectations" regarding the Application and its clinical support. See

[19] See also In re Secure Computing Corp. Sec. Litig., 120 F. Supp. 2d 810, 818 (N.D. Cal. 2000) ("By stating that Secure was on track to meet expectations, Defendants represented that a reasonable person who knew what Defendants knew at the time the statements were made could reasonably conclude that Secure was likely to meet analysts' expectations. Considered as statements of current business conditions, these statements were not forward-looking.").

Killinger, 399 F. Supp. 2d at 1133. Although these statements "relate" to the forward-looking statements predicting FDA approval, they are not "assumptions" and thus they are not covered by the safe harbor. 15 U.S.C. § 78u-5(i)(1).[20]

III. Loss Causation

Defendants argue plaintiffs have not adequately pleaded loss causation. The complaint must provide "defendants with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the alleged misrepresentation." Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005). In Dura, the Court assumed without deciding that allegations of loss causation need only satisfy Rule 8 of the Federal Rules of Civil Prcoedure, and are not subject to the heightened pleading standards of Rule 9 or the PSLRA. Ninth Circuit courts interpreting Dura have not required plaintiffs to plead loss causation with particularity. See In re Daou Sys., Inc., 411 F.3d 1006, 1025 (9th Cir. 2005) (requiring plaintiff to show "some causal connection" between the fraud and the securities transaction in question); In re Immune Response Sec. Litig., 375 F. Supp. 2d 895, 1025 (S.D. Cal. 2005) (noting Rule 8 applies to loss causation).

Plaintiffs' allegations of loss causation would be plausible if the complaint adequately alleged falsity and scienter. The FDA's non-approval letter could have corrected misrepresentations and omissions regarding the sufficiency of the data in the Application. After receiving the non-approvable letter, defendants made optimistic statements the deficiencies could be cured. Pfizer's termination of the collaboration on indiplon could have signalled to the market these statements were inaccurate and the Application would never be approved. Accordingly, the Court finds the allegations of loss causation are sufficient.[21]

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[20] In re Syntex Corp. Securities Litigation, 95 F.3d 922, 931-33 (9th Cir. 1996), cited by defendants in their briefs and during oral argument, is not to the contrary. In that case, the court found statements of fact supporting forward-looking statements were forward-looking, but also noted plaintiffs had not pleaded facts showing that the statements were false when made. Id. In this case, the Court finds the statements could have been false when made, but plaintiffs have not adequately pleaded falsity and scienter. Accordingly, the Court takes a slightly different approach with the same result.

[21] Defendants also argue the outside directors, Pops and Vale, should be dismissed because no allegations link them to knowledge the 15 mg data was insufficient or link them to any of the statements asserting the sufficiency of the data. The Court agrees. If plaintiffs file an amended complaint, it must contain particularized allegations which raise a compelling inference each of the individual defendants had the required state of mind.

Leave to Amend

The Court may dismiss a complaint without granting leave to amend only if it appears with certainty the plaintiff cannot state a claim and any amendment would be futile. See Fed. R. Civ. P. 15(a) (stating that leave to amend "shall be freely given when justice so requires"); DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992); Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986) (stating "leave to amend should be granted unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency"). In this case, the Court finds leave to amend is appropriate to allow plaintiffs an opportunity to cure the deficiencies described in this Order.

CONCLUSION

For the foregoing reasons, the Court hereby GRANTS defendants' motion to dismiss the complaint. The Court GRANTS plaintiffs leave to file an amended complaint within thirty (30) days of the date of this Order. If plaintiffs file an amended complaint, they shall also file a "red-lined" version indicating the changes made.

The Court also GRANTS IN PART and DENIES IN PART plaintiffs' motions to strike. The Court DENIES defendants' request for judicial notice of Exhibits A, B, D, F, and I and GRANTS plaintiffs' motion to strike those exhibits. The Court GRANTS judicial notice of Exhibits C, G, T, W-Z, and AA-AI, which plaintiffs have not moved to strike. Finally, the Court GRANTS defendants' request for judicial notice of Exhibits J-M, O-S, U, and AJ-AP and DENIES plaintiffs' motion to strike those exhibits. The Court finds Exhibits E, H, N, V, and AQ-AT unnecessary to consider and therefore DENIES AS MOOT defendants' request for judicial notice of these exhibits, and DENIES AS MOOT plaintiffs' motion to strike these exhibits. Judicial notice is only granted for the purposes noted in this Order.

IT IS SO ORDERED.

DATED: May 12, 2008

IRMA E. GONZALEZ, Chief Judge
United States District Court